Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/RU2004/000261	International filing date *(day/month/year)* 01.07.2004	Priority date *(day/month/year)* 14.07.2003
International Patent Classification (IPC) or national classification and IPC A61K38/43, 39/395, A61P35/00		
Applicant GENKIN, Dmitry Dmitrievich		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of _____ sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

   a. ☐ *(sent to the applicant and to the International Bureau)* a total of _____ sheets, as follows:

      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s))

      _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/RU Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/RU2004/000261

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:

☐ international search (Rule 12.3 and 23.1(b))

☐ publication of the international application (Rule 12.4)

☐ international preliminary examination (Rule 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☐ the international application as originally filed/furnished

☐ the description:

pages _____ as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the claims:

nos. _____ as originally filed/furnished

nos.* _____ as amended (together with any statement) under Article 19

nos.* _____ received by this Authority on _____

nos.* _____ received by this Authority on _____

☐ the drawings:

sheets _____ as originally filed/furnished

sheets* _____ received by this Authority on _____

sheets* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/RU2004/000261

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-14	YES
	Claims		NO
Inventive step (IS)	Claims	2-4, 6, 8-11, 14	YES
	Claims	1, 5, 7, 12-13	NO
Industrial applicability (IA)	Claims	1-11	YES
	Claims	12-14	NO

2. Citations and explanations (Rule 70.7)

This report has been established taking into account the applicant's reply of 15.02.2005, and the following documents:

D1: RU 2001104426 A 20.01.2003

D2: US 6521409 19.02.2003

D3: MUTIRANGURA A. Ann N Y Acad. Sci., 2001 Sep; 945; 59-67

D4: US 5484589 A

The method characterised in claims 1-14 meets the requirement of novelty, as it is not disclosed in the known prior art, in particular D1-D4.

However, D1-D4 are prejudicial to recognition that the method according to claims 1, 5, 7, 12 and 13 involves an inventive step, as this method is obvious to a person skilled in the art.

Thus it is known from D1 to treat an oncological disease by means of a DNA-destroying chemical composition. The pathogenetic significance of blood extracellullar DNA, in particular of a viral nature, in the emergence and development of oncological diseases is known from D2 and D3. Moreover, the curative effect of

administering a DNA-destroying agent (DNase) into systemic blood circulation in case of a pathological process connected with blood extracellular DNA is known from D4. The possibility of using recombinant DNase and combined administration of DNase and ribonuclease for these purposes also follows from D4.

As regards the method according to claims 1, 5, 7, 12 and 13, the applicants note that D1 relates to treatment of oncological diseases by means of an agent which destroys intracellular DNA, which differs from the claimed method, in which this agent destroys blood extracellular DNA.

However, the examiner does not agree with the applicants' assertion, because D1 describes only agents which destroy DNA and in so doing produce an anti-tumour effect. It does not follow from D1 precisely which DNA is destroyed.

In their reply the applicants emphasise that the agents acting on DNA are not specific. It may be deduced that any agent capable of destroying DNA will be effective for both cellular and extracellular DNA when administered into the body.

The applicants agree that blood extracellular DNA is pathogenetically significant for the emergence and development of oncological diseases (D2 and D3). Therefore, taking into account D1, it is obvious to a person skilled in the art that an anti-tumour effect is produced when an agent is administered which destroys, inter alia, blood extracellular DNA.

Therefore, the methods characterised in claims

1, 5, 7, 12 and 13 do not meet the requirement of inventive step.

Other particular embodiments of the method according to claims 2-6, 8, 9-11 and 14 can be recognised as meeting the requirement of inventive step, as these methods do not follow obviously from D1-D4.

The methods characterised in claims 1-11 meet the requirement of industrial applicability.

However, the methods according to claims 12-14 do not meet the requirement of industrial applicability, as the prior art does not identify nor the description present information to the effect that agents exist which can simultaneously change the chemical composition, conformation, polymery, and association with other substances of blood extracellular DNA. Implementation of such variants of the method according to claims 12, 13 and 14 does not, therefore, appear to be possible.

In their reply the applicants present information as to which agents should be considered to change the chemical composition of the DNA, and which agents to change the conformation or polymery of DNA, or the association thereof with proteins, lipids and nucleic acids. This information, however, does not invalidate the question as to whether a number of variants of the method can be realised, as the use is proposed therein of agents whose characterisation applies to a drug that changes chemical composition, conformation, polymery, and association with proteins, lipids and ribonucleic

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

acids simultaneously. It should be noted again that the prior art does not identify such agents, and the arguments of the applicants as to the possibility of their existence are not convincing. Therefore, neither the original materials of the application nor the applicants' reply confirms the possibility of treating oncological diseases using all the methods and variants according to claims 12-14.